

Application No. 10/085,142
Response to Final Office Action Dated November 2, 2006
Amendment dated February 2, 2007

REMARKS

Claims 42-45 and 48 remain in the application. By this Amendment, claims 46 and 47 have been canceled hereby without prejudice or disclaimer. New claims 49-58 have been added without adding new matter. Thus, claims 42-45 and 48-58 are pending.

The final Office Action dated November 2, 2006, rejected claims 42-48 as failing to comply with 35 U.S.C. §112, first and second paragraphs. The final Office Action also objected to claims 42 and 46 for informalities. This amendment duly responds to the objections and rejections in the final Office Action dated November 2, 2006. Entry of this amendment, reconsideration, and favorable action, are respectfully requested.

Claim Objections

The final Office Action, at page 2, objected to claims 42 and 46 for informalities in labeling steps or features. Applicants have corrected the labeling as appropriate. The objection is overcome. Reconsideration and withdrawal of the objection are respectfully requested.

Claim Rejections – 35 U.S.C. §112, Second Paragraph

The final Office Action, at page 3, rejected claims 42-48 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse the rejection.

The final Office Action asserts that the term “polymorphic analysis” in claim 42 is not clear. Applicants respectfully submit that term would be understood by persons skilled in the art in

Application No. 10/085,142

Response to Final Office Action Dated November 2, 2006

Amendment dated February 2, 2007

connection with genotype classification, including to identify single nucleotide polymorphisms (SNPs) or other polymorphisms, as, for example, noted at page 1, lines 21-27 of Applicants' specification. To advance progress of the application, however, Applicants have amended claim 42 to delete reference to that term. The rejection on those grounds is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The final Office Action asserted that the term "a next" in claim 42, step (e), is not clear. Applicants respectfully submit that term would be adequately clear to persons skilled in the art to refer to successive or adjoining values. To advance progress of the application, Applicants have, however, amended claim 42 to refer to "current" and "previous" values, as, for example, described in Applicants' specification at page 7, lines 7-12. The rejection on those grounds is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The final Office Action asserted that the term "locality" in claim 42, step (g) is indefinite. Applicants respectfully submit that the term "locality" would be adequately clear to persons skilled in the art as referring to the location or position of the probe pairs with respect to the at least one category-angular value. To advance progress of the application, however, Applicants have amended claim 42 to delete reference to that term. The rejection on those grounds is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The final Office Action asserted that the term "predetermined condition" in claim 46 is unclear. Applicants respectfully submit that the term "predetermined condition" in claim 46 would be adequately clear to persons skilled in the art as referring to as one of any number of conditions in the data set, metrics characterizing the data set, or other conditions such as those described in

Application No. 10/085,142

Response to Final Office Action Dated November 2, 2006

Amendment dated February 2, 2007

Applicants' specification at page 8, lines 10-28, or elsewhere that can cause a classification of datapoints as undetermined. Applicants have, however, canceled claim 46 so that this rejection is made moot. The rejection is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections – 35 U.S.C. §112, First Paragraph

The final Office Action, at page 4, rejected claims 46-48 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, and representing new matter. The final Office Action indicated that identifying at least one pair of probes as undetermined based on at least one predetermined condition was not taught in the specification. Applicants respectfully traverse the assertion that identifying probe pairs as undetermined based on at least one predetermined condition is not adequately taught or described in Applicants' specification.

The Examiner's attention is directed, for example, to Applicants' specification at page 8, lines 26-28, which states that “[t]he average distance of all remaining datapoints is then computed and used to calculate a threshold. All remaining datapoints that fall below this threshold are predicted as undetermined and removed from further classification.” Other predetermined conditions are described in Applicants' specification, for example, at page 9, line 4 – page 10, line 21, and elsewhere. Applicants have, however, canceled claim 46 and 47, so that this rejection of those claims is made moot. Claim 48 has been amended, and does not refer to “predetermined conditions,” so that the rejection of claim 48 on those grounds is also made moot. The rejection is

Application No. 10/085,142
Response to Final Office Action Dated November 2, 2006
Amendment dated February 2, 2007

overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The final Office Action rejected claims 42-48 under 35 U.S.C. §112, first paragraph on grounds that the specification, while being enabling for the identification of clusters from genotypic fluorescence data which has no overlap between potential clusters, does not reasonably provide enablement for identification of clusters from any genotypic fluorescence data in general, e.g., data for which potential clusters overlap. Applicants respectfully traverse the assertion that Applicants' specification does not reasonably provide enablement for identification of clusters from general genotypic fluorescence data.

The final Office Action points out an example of fluorescence probe-pair data, reflected in the article by Rao et al., particularly Fig. 5a of that publication, for which the final Office Action asserted the recited method would not be enabled. Applicants respectfully point out that the only truly overlapping data clusters in Fig. 5a of that publication are controls (shown in the lower left box). Controls can, for example, be eliminated from further classification in various embodiments of Applicants' teachings, for example as described at page 8, lines 7-9. Otherwise, the scenario pointed out in the final Office Action is merely clusters having inadequate separation.

Methods according to various embodiments of Applicants' teachings could still operate to classify those clusters, for example into just one cluster, or multiple clusters, albeit with potentially greater or lesser accuracy in terms of allelic or other results. According to various embodiments, methods according to Applicants' teachings could also refrain from classifying datapoints into clusters, for example, to label or remove data as invalid or undetermined. Applicants' specification, as noted above, furthermore describes tests or conditions that can be used to catch potentially

inaccurate data, for instance to flag that data for operator review. See, e.g., specification page 9, line 4 - page 10, line 21. Applicants respectfully submit that Applicants' method is adequately enabled by the specification, claims and drawings as originally filed, including for data sets having borderline probe pairs.

To advance progress of the application, however, Applicants have amended claim 42 to even more particularly recite features of "(f) determining if the angular difference value of at least one of the ordered set of angular values differs from the previous angular difference value by at least a predetermined difference threshold." Claim 42 also includes features of "(g) if the angular difference value of at least one of the ordered set of angular values is determined to differ from one previous angular value by at least the predetermined difference threshold, determining at least one category-dividing value based on the at least one of the ordered set of angular values."

Claim 42 further includes features of "(h) classifying the genotype of the DNA sample based on the plotted fluorescence dye emissions of each probe pair with respect to the at least one category-dividing angular value to generate classification results when the at least one category-dividing angular value is identified." Applicants respectfully submit that the rejection of claims 42-48 under 35 U.S.C. §112, first paragraph, for alleged lack of enablement is overcome, since claim 42 includes features of "classifying the genotype... when the at least one category-dividing angular value is identified," so that classification in the method as claimed is dependent or conditional on identification of at least one category-defining value. This is consistent with, and supported by, Applicants' specification, for example, at page 7, lines 13-15, where it is stated that "[i]f the difference value [of angular values] is large enough to exceed a predetermined threshold, a new

Application No. 10/085,142
Response to Final Office Action Dated November 2, 2006
Amendment dated February 2, 2007

category-dividing value is designated between the two angle values from which that difference value was calculated.” The rejection of claim 42 under 35 U.S.C. §112, first paragraph, for lack of enablement is overcome. The rejection is respectfully traversed. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 43-45 and 48 overcome the rejection 35 U.S.C. §112, first paragraph, for alleged lack of enablement, for at least the same reasons as claim 42, from which they depend, does. The rejection of claims 43-45 and 48 under 35 U.S.C. §112, first paragraph, for lack of enablement is overcome. The rejection is respectfully traversed. Reconsideration and withdrawal of the rejection are respectfully requested.

New Claims 49-58

New claims 49 -58 have been added without adding new matter. These new claims avoid the objections and rejections raised in the final Office Action. Favorable consideration is respectfully requested.

CONCLUSION

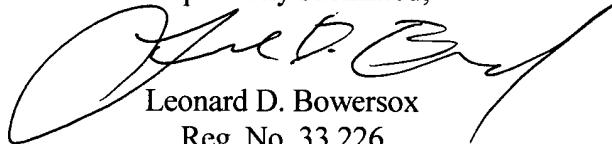
In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration of the present application and a timely allowance of the pending claims.

Should the Examiner deem that any further action by Applicants or Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

Application No. 10/085,142
Response to Final Office Action Dated November 2, 2006
Amendment dated February 2, 2007

If there are any other fees due in connection with the filing of this response, please charge the fees to deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



Leonard D. Bowersox
Reg. No. 33,226
Scott D. Balderston
Reg. No. 35,436

KILYK & BOWERSOX, P.L.L.C.
3603-E Chain Bridge Road
Fairfax, Virginia 22030
Tel.: (703) 385-9688
Fax.: (703) 385-9719